Attachment 7 APR 19 2006

510(k) SUMMARY
PROBEAT with MGCS

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

K060834

Hitachi, Ltd., Power Systems Group
Advanced Medical Technology and Solutions Division, Proton Therapy
18-13, Sotokanda 1-chome, chiyoda-ku
Tokyo, 101-8608
Japan

Phone : 011-81-3-4564-3565
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Contact Person: Naoya Nishimura

Date Prepared: March 27, 2006

Name of Device and Name/Address of Sponsor

PROBEAT

Hitachi, Ltd., Power Systems Group
Advanced Medical Technology and Solutions Division, Proton Therapy
18-13, Sotokanda 1-chome, chiyoda-ku
Tokyo, 101-8608
Japan

Common or Usual Name: Proton Beam Therapy System ("PBTS")
Classification Name: Medical Charged-Particle Radiation Therapy System
Predicate Device: Hitachi's PROBEAT (K053280)
Purpose of the Special 510(k) notice.

The PROBEAT with MGCS is a modification to Hitachi's cleared PROBEAT.

Intended Use

The PROBEAT with MGCS is a medical device designed to produce and deliver a proton beam for the treatment of patients with localized tumors and other conditions susceptible to treatment by radiation. The only difference between the PROBEAT with MGCS and the cleared PROBEAT is the addition of the MGCS that

converts the scale and format of the dimensional data of the patient specific aperture and/or compensator generated by commercially available patient treatment planning/management software into the scale and format used by an industrial, computer controlled milling machine to enable the milling machine to fashion the required aperture or compensator for patient treatment, do not raise any new questions of safety or effectiveness.

Technological Characteristics

The PROBEAT with MGCS is a proton beam irradiation system, which provides a therapeutic proton beam for clinical treatment. It is designed to deliver a proton beam with the prescribed dose, dose distribution and directed to the prescribed patient treatment site. The PBTS is designed to be safe and reliable. The equipment to perform the above work is comprised of two main components. One is a beam delivery system whose primary responsibility is to ensure that the above listed prescription parameters are properly delivered. The other is the equipment necessary to generate the proton beam and direct it to the beam delivery system

Performance Data

The submission includes performance testing that Hitachi conducted to demonstrate that the device meets its performance specifications.

Substantial Equivalence

The PROBEAT with MGCS device has the same intended use and indications for use, similar principles of operation, and similar technological characteristics as the previously cleared predicate PROBEAT. The only difference between the PROBEAT with MGCS and the cleared PROBEAT is the addition of the MGCS that converts the scale and format of the dimensional data of the patient specific aperture and/or compensator generated by commercially available patient treatment planning/management software into the scale and format used by an industrial, computer controlled milling machine to enable the milling machine to fashion the required aperture or compensator for patient treatment. The addition of the MGCS to the PROBEAT does not raise any new questions of safety or effectiveness. Performance data demonstrate that the PROBEAT with MGCS is as safe and effective as the cleared PROBEAT. Thus, the PROBEAT with MGCS is substantially equivalent to its predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

APR 19 2006

Hitachi, Ltd. Power Systems Group
% Mr. Jonathan S. Kahan, Esq.
Regulatory Counsel
Hogan & Hartson L.L.P
555 Thirteenth Street, NW
WASHINGTON DC 20004

Re: K060834
Trade/Device Name: PROBEAT with MGCS
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: LHN
Dated: March 27, 2006
Received: March 27, 2006

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment 8

Indications for Use Statement

510(k) Number (if known): K060834

Device Name: PROBEAT with MGCS

Indications for Use: Hitachi's PROBEAT with MGCS is a medical device designed to produce and deliver a proton beam for the treatment of patients with localized tumors and other conditions susceptible to treatment by radiation.

Prescription Use ✓ (Per 21 C.F.R. 801.109) AND/OR Over-The-Counter Use ___ (Per 21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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David G. Segerson

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K060834

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